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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Darren A. Janzig; Carl D. Wahlstrand; Robert M. Skime; Mark S. Lent; Keith A. Miesel; James E. Cabak	Confirmation No.	3259
Serial No.:	10/731,699		
Filed:	December 9, 2003	Customer No.:	28863
Examiner:	George C. Manuel		
Group Art Unit:	3762		
Docket No.:	1023-331US01		
Title:	COUPLING MODULE OF A MODULAR IMPLANTABLE MEDICAL DEVICE		

APPEAL BRIEF

Mail Stop: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is an Appeal Brief responsive to the Office Action mailed October 25, 2007 and the Advisory Action dated February 14, 2008. Appellant filed a Notice of Appeal on February 25, 2008 with a one-month extension of time. Accordingly, the due date for this Appeal Brief is April 25, 2008.

Please charge Deposit Account No. 50-1778 in the amount of $510.00 for Appellant's appeal brief fee, as required by 37 C.F.R. §41.37(a)(2).

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By: _____
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REAL PARTY IN INTEREST

The real party in interest is Medtronic, Inc. of Minneapolis, Minnesota.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

STATUS OF CLAIMS

Claims 1, 3-11, 13-15 and 17-25 are on appeal in this case.

Claims 7-11, 14, 15, 17 and 20-23 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hirschberg et al. (US 5,312,440, hereinafter "Hirschberg").

Claim 25 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Lynch (US 4,934,368).

Claims 1, 3-6 and 24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lynch.

Claims 7, 8, 19 and 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Meltzer (US 5,645,586).

Claims 12, 13, 18 and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hirschberg.

Claim 1 also stands rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending US Pat. No. 7,212,864.

Claims 2, 12 and 16 are currently canceled and are not on appeal.

STATUS OF AMENDMENTS

The claims on appeal are those submitted in the Amendment filed on January 25, 2008 in response to the Final Office Action mailed October 25, 2007. By the Amendment filed on January 25, 2008, claim 12 was cancelled. The Amendment was entered by the Examiner according to the Advisory Action dated April 10, 2008.

SUMMARY OF CLAIMED SUBJECT MATTER

The claims on appeal include three independent claims: claims 1, 7 and 25, each of which is directed to an implantable medical device.[1] Claims 3-6 and 24 are dependent on claim 1, while claims 8-11, 13-15 and 17-23 are dependent on claim 7.[2] None of the claims on appeal include a means plus function or step plus function as permitted by 35 U.S.C. § 112, sixth paragraph.[3]

The implantable medical device of claim 1 comprises at least two modules, each of the modules comprising a respective one of at least two housings,[4] a coupling module coupled to each of the modules,[5] the coupling module defining at least one lumen between the housings,[6] and an overmold that at least partially encapsulates each of the housings and the coupling module.[7] The coupling module permits motion of the two modules along at least one axis of motion.[8]

Appellant's invention as recited by claim 7 is directed to an implantable medical device comprising a first module that includes control electronics[9] comprising a first housing, a second module comprising a second housing,[10] and a coupling module fixedly coupled to the first and second housings.[11] The coupling module is hermetically fixed to the first and second housings.[12] The coupling module is made of a metal[13] that defines at least one lumen between the first and second housings.[14] The coupling module permits motion of the first housing relative to the second housing and along at least one axis of motion.[15]

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[1] *See* claims 1, 7 and 25.
[2] *See* claims 3-6, 8-11, 13-15 and 17-24.
[3] *See* claims 1, 3-11, 13-15 and 17-25.
[4] *See, e.g.*, Application, paragraphs [0045] and [0061] and FIGS. 4A-4F, 16A and 16B.
[5] *See, e.g.*, Application, paragraphs [0008], [0009] and [0058]-[0066] and FIGS. 6A-6C, 7A, 7B, 8, 16A and 16B.
[6] *See, e.g.*, Application, paragraphs [0061], [0069] and [0071]-[0075] and FIGS. 6A-6C, 10A-10I, 16A and 16B.
[7] *See, e.g.*, Application, paragraphs [0038], [0039], [0045], [0048]-[0056] and [0084]-[0089] and FIGS. 4A-4F, 5A-5C, 15A,15B 16A and 16B.
[8] *See, e.g.*, Application, paragraphs [0058]-[0066] and FIGS. 6A-6C, 7A, 7B and 8.
[9] *See, e.g.*, Application, paragraphs [0011], [0037] and [0040] and FIGS. 1B and 2.
[10] *See, e.g.*, Application, paragraphs [0004], [0005], [0045] and [0061] and FIGS. 4A-4F, 16A and 16B.
[11] *See, e.g.*, Application, paragraphs [0008], [0009], [0011] and [0058]-[0066] and FIGS. 6A-6C, 7A, 7B, 8, 16A and 16B.
[12] *See, e.g.*, Application, paragraphs [0061] and [0068].
[13] *See, e.g.*, Application, paragraph [0066].
[14] *See, e.g.*, Application, paragraphs [0061], [0069] and [0071]-[0075] and FIGS. 6A-6C, 10A-10I, 16A and 16B.
[15] *See, e.g.*, Application, paragraphs [0058]-[0066] and FIGS. 6A-6C, 7A, 7B and 8.

Appellant's invention as recited by claim 25 is directed to an implantable medical device comprising a first module that includes control electronics[16] comprising a first housing; a second module comprising a second housing;[17] and a coupling module fixedly coupled to the first and second housings.[18] The coupling module is hermetically fixed to the first and second housings[19] and defines at least one lumen between the first and second housings.[20] The coupling module permits motion of the first housing relative to the second housing and along at least one axis of motion.[21]

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant submits the following grounds of rejection to be reviewed on Appeal:

(1) The first ground of rejection to be reviewed is the rejection of claim 25 under 35 U.S.C. § 102(b) as being anticipated by Lynch (US 4,934,368).

(2) The second ground of rejection to be reviewed is the rejection of claims 7-11, 14, 15, 17 and 20-23 under 35 U.S.C. § 102(b) as being anticipated by Hirschberg et al. (US 5,312,440, hereinafter "Hirschberg").

(3) The third ground of rejection to be reviewed is the rejection of claims 12, 13, 18 and 19 under 35 U.S.C. § 103(a) as being unpatentable over Hirschberg.

(4) The fourth ground of rejection to be reviewed is the rejection of claims 1, 3-6 and 24 under 35 U.S.C. § 103(a) as being unpatentable over Lynch.

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[16] *See, e.g.*, Application, paragraphs [0011], [0037] and [0040] and FIGS. 1B and 2.
[17] *See, e.g.*, Application, paragraphs [0004], [0005], [0045] and [0061] and FIGS. 4A-4F, 16A and 16B.
[18] *See, e.g.*, Application, paragraphs [0008], [0009], [0011] and [0058]-[0066] and FIGS. 6A-6C, 7A, 7B, 8, 16A and 16B.
[19] *See, e.g.*, Application, paragraphs [0061] and [0068].
[20] *See, e.g.*, Application, paragraphs [0061], [0069] and [0071]-[0075] and FIGS. 6A-6C, 10A-10I, 16A and 16B.
[21] *See, e.g.*, Application, paragraphs [0058]-[0066] and FIGS. 6A-6C, 7A, 7B and 8.

(5) The fifth ground of rejection to be reviewed is the rejection of claims 7, 8, 19 and 25 under 35 U.S.C. § 103(a) as being unpatentable over Meltzer (US 5,645,586).

(6) The sixth ground of rejection to be reviewed is the rejection of claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending US Pat. No. 7,212,864.

ARGUMENT

Appellant respectfully traverses the current rejections advanced in the Final Office Action, and requests reversal by the Board of Patent Appeals based on the arguments below. Appellant respectfully requests separate review of each set of claims argued under separate headings.

An invention that is anticipated by a prior art reference is not patentable. In order to support an anticipation rejection under 35 U.S.C. § 102(b), it is well established that a prior art reference must disclose each and every element of a claim. This well known rule of law is commonly referred to as the "all-elements rule."[22] If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. § 102(b) is improper.[23]

In addition, an invention that would have been obvious to a person of ordinary skill at the time of the invention is not patentable.[24] The Supreme Court recently clarified the standard of non-obviousness under 35 U.S.C. § 103(a) in *KSR Int'l Co. v. Teleflex, Inc.*[25] As reiterated by the Supreme Court in *KSR International Co.* v. *Teleflex Inc.* (KSR),[26] the framework for the objective analysis for determining obviousness under 35 U.S.C. § 103 is stated in *Graham* v. *John Deere Co.*[27] Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

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[22] *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (CAFC 1986) ("it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention").
[23] *Id. See also Lewmar Marine, Inc. v. Barient, Inc.* 827 F.2d 744, 3 USPQ2d 1766 (CAFC 1987); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ2d 1225 (CAFC 1998); *Oney v. Ratliff*, 182 F.3d 893, 51 USPQ2d 1697 (CAFC 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (CAFC 2000).
[24] 35 U.S.C. § 103(a).
[25] *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. ____ (case 04-1350) (April 30, 2007).
[26] 550 U.S. _, 82 USPQ2d 1385 (2007).
[27] 383 U.S. 1, 148 USPQ 459 (1966).

(1) Determining the scope and content of the prior art;

(2) Ascertaining the differences between the claimed invention and the prior art; and

(3) Resolving the level of ordinary skill in the pertinent art.

In *KSR*, the Supreme Court explained that the Examiner must identify a logical reason why a person of ordinary skill in the art would have been led to make a modification or combination to arrive at the claimed invention. An invention composed of several elements is not proved obvious merely by demonstrating that each of the elements was independently known.[28]

Consistent with *KSR*, the Federal Circuit has stated that there must be "some rationale, articulation, or reasoned basis" to support the legal conclusion of obviousness."[29] The reason for modification need not conform to the particular motivation or objective of the patent Appellant.[30] However, there still must be some need or problem known in the art that would have provided a reason for combining elements in the manner claimed.[31]

The *KSR* case clarified that the "suggestion or motivation" requirement is more broadly a requirement that the Examiner articulate a "rational reason" for the modification. However, if there is no *rational* reason a person of ordinary skill in the art would have arrived at the claimed invention in view of the prior art, the obviousness rejections must be reversed.

FIRST GROUND OF REJECTION UNDER APPEAL

GROUP I - (Claim 25)

Appellant's independent claim 25 is directed to an implantable medical device comprising a first module that includes control electronics comprising a first housing; a second module comprising a second housing; and a coupling module fixedly coupled to the first and second housings. The coupling module is hermetically fixed to the first and second housings[32] and defines at least one lumen between the first and second housings. The coupling module

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[28] *KSR*, Slip op. at 14.
[29] *Alza Corp. v. Mylan Laboratories*, 80 USPQ2d 1001, 1005 (Fed. Cir. 2006) (citing *In re Kahn*, 78 USPQ2d 1329 (Fed. Cir. 2006)).
[30] *KSR*, Slip op. at 16.
[31] *Id.*
[32] *See, e.g.*, Application, paragraphs [0061] and [0068].

permits motion of the first housing relative to the second housing and along at least one axis of motion.

The Office Action rejected claim 25 under 35 U.S.C. § 102(b) as being anticipated by Lynch (US 4,934,368). Appellant respectfully traverses the rejection. Lynch fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and furthermore provides no teaching that would have suggested the desirability of modification to include such features.

In the rejection of claim 25, the Office Action cited implant case 12 and nerve cuff 2 of the neurological stimulation apparatus disclosed by Lynch as respectively being equivalent to the first module and the second module recited in claim 25. The Office Action also cited lead 3 as being equivalent to the coupling module as recited in claim 25. The Office Action further stated that lead 3 is inherently hermetically sealed to both implant case 12 and nerve cuff 2 using silicon rubber.

The Office Action failed to cite any support for the contention that lead 3 is inherently hermetically sealed to both implant case 12 and nerve cuff 2 using silicone rubber. Appellant strongly disagrees that such a feature is inherent in the neurological stimulation apparatus disclosed by Lynch. Instead, Lynch actually teaches away fromthe concept that implant case 12 and nerve cuff 2 are each hermetically sealed to lead 3.

For example, Lynch discloses that master circuitry case 8 is hermetically sealed, but fails to mention that either implant case 12 or nerve cuff 2 is hermetically sealed to lead 3. Because Lynch explicitly discusses hermetic sealing in another context, i.e., with respect to master circuitry case 8, one of ordinary skill in the art would not have interpreted Lynch's silence with respect to the coupling of implant case 12 or nerve cuff 2 lead 3 to mean that such coupling was inherently hermetic. Furthermore, one of ordinary skill in the art would not have expected that hermetical sealing of implant case 12 or nerve cuff 2 of Lynch would have been necessary, and therefore would not have considered such hermetic sealing to have been necessarily present in the Lynch device as required for a finding of inherency.[33] For reference, FIG. 3 and FIG. 4 of Lynch are reproduced below.

[33] The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993), as cited in MPEP § 2112 (IV).

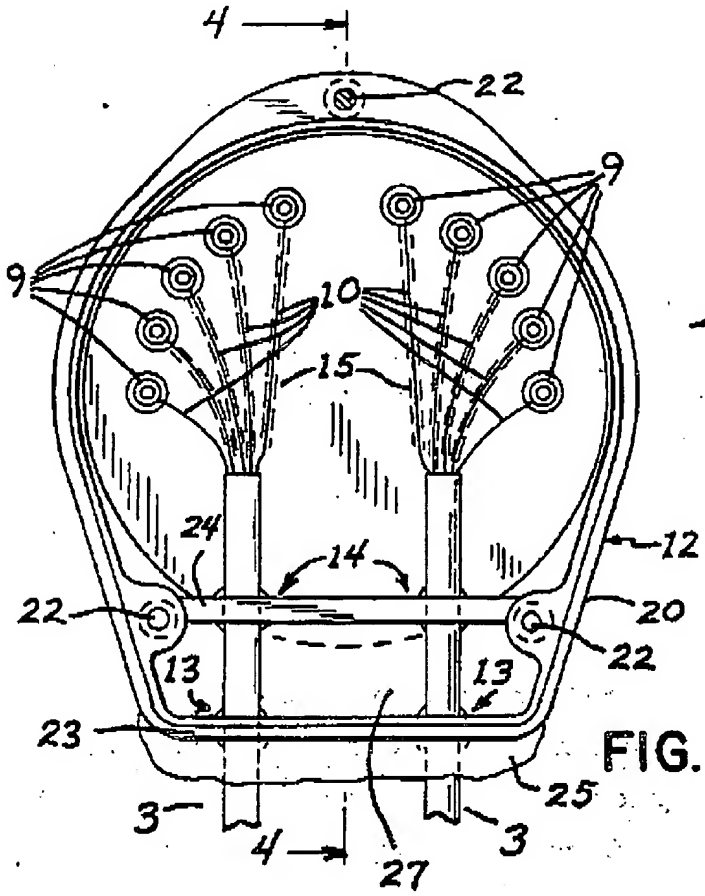

FIG. 4

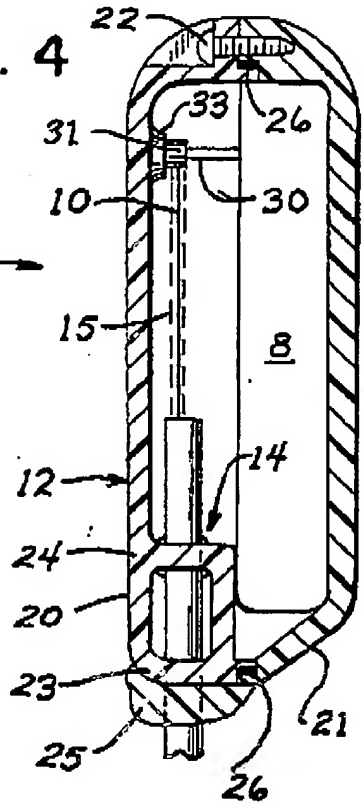

FIG. 3

As mentioned previously, Lynch discloses that master circuitry case 8 is hermetically sealed to protect master circuit 6 from contamination.[34] Lynch then discloses that hermitically sealed master circuitry case 8 is enclosed in implant case 12 and that implant case 12 provides "positive environmental protection" for the termination of the leads 3 into master circuitry case 8 via outer seal 13 and inner seal 14.[35] Notably, outer seal 13 and inner seal 14 are not described as providing a hermetic seal, but "positive environmental protection." From this context, one can assume that positive environmental protection refers to a level of sealing different than a hermetic seal. Furthermore, because master circuitry case 8 is disclosed as being hermetically sealed, and because master circuitry case 8 is contained entirely within implant case 12, which provides positive environmental protection, one of skill in the art would assume that positive environmental protection is a level of sealing that is less than hermetic sealing.

[34] Lynch, column 6, lines 20-21.
[35] Lynch, column 6, lines 40-47.

Indeed, if implant case 12 were hermetically sealed, then there would be no reason that master circuitry case 8 would need to be hermetically sealed as master circuitry case 8 is contained entirely within implant case 12. Hermetically sealing both implant case 12 and master circuitry case 8 would add unnecessary expense to the manufacture of a neurological stimulation apparatus disclosed by Lynch.

With respect to the connection between lead 3 and nerve cuff 2, Lynch fails to teach or suggest any level of sealing, much less a hermetic connection between lead 3 and nerve cuff 2.

Furthermore, disclosure of Lynch actually demonstrates that silicone rubber does not provide a hermetic seal as asserted in the Office Action. As disclosed by Lynch, implant case 12 includes outer seal 13 and inner seal 14 to provide positive environmental protection at the interface with lead 3. Lynch also discloses silicon rubber 25 outside implant case 12 at the interface with lead 3 for the purpose of absorbing lateral strain on lead 3.[36] Lynch fails to mention that silicon rubber 25 has any sealing qualities whatsoever. If silicon rubber 25 provided a hermetic seal as asserted by the Office Action, then outer seal 13 and inner seal 14 would serve no purpose whatsoever. For at least these reasons, it is apparent that silicon rubber 25 does not provide a hermetic connection between implant case 12 and lead 3. Likewise, the silicon dip coating does not provide a hermetic connection between implant case 12 and nerve cuff 2.

As set out in MPEP 2112 (IV), the Office Action, "must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."[37] In this case, because the Office Action fails to teach or suggest any reasoning to support the finding of inherency, the current rejection fails to meet this standard. Additionally, the feature of a coupling module hermetically fixed to the first and second housings is clearly not taught or suggested by Lynch.

Lynch fails to teach or suggest each and every element of claim 25. For at least these reasons, the Office Action fails to establish anticipation of Appellant's claims 25 under 35 U.S.C. § 102(b). Reversal of this rejection is requested.

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[36] Lynch, column 7, lines 1-6.
[37] *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

SECOND GROUND OF REJECTION UNDER APPEAL

The Office Action rejected claims 7-11, 14, 15, 17 and 20-23 under 35 U.S.C. § 102(b) as being anticipated by Hirschberg et al. (US 5,312,440, hereinafter "Hirschberg"). Appellant respectfully traverses the rejection. Hirschberg fails to teach each and every feature of the claimed invention, as required by 35 U.S.C. § 102 (b), and furthermore provides no teaching that would have suggested the desirability of modification to include such features.

Appellant's independent claim 7 is directed to an implantable medical device comprising a first module that includes control electronics comprising a first housing, a second module comprising a second housing, and a coupling module fixedly coupled to the first and second housings. The coupling module is hermetically fixed to the first and second housings. The coupling module is made of a metal that defines at least one lumen between the first and second housings. The coupling module permits motion of the first housing relative to the second housing and along at least one axis of motion.

GROUP 2 - (Claims 7, 8, 11 and 20-23)

With respect to independent claim 7, Hirschberg fails to teach or suggest a coupling module that is made of a metal that defines at least one lumen. In the rejection of claim 7, the Office Action cited lead 9 of Hirschberg as being equivalent to the coupling module recited in claim 7. However, in contrast to the coupling module recited in claim 7, lead 9 is not made of a metal that defines at least one lumen. Nothing in Hirschberg remotely suggests that lead 9 is made of metal that defines a lumen. Assuming, for the sake of argument, that lead 9 includes metal, e.g., a conductor, such metal does not define a lumen, as required by independent claim 7.

As another example, with respect to independent claim 7, Hirschberg fails to teach or suggest the feature of wherein the coupling module is hermetically fixed to the first and second housings. The Office Action asserted that such a feature would be inherent to prevent bodily fluids from entering and shorting the electrical connections. The Office Action failed to provide any support for this assertion. Appellant disagrees that hermetic fixation would be necessary or obvious to prevent shorting in the Hirschberg device.

Hirschberg discloses that terminals 7 and 16, where a first section 18 of lead 9 connects to housings 2 and 15, are in the form of insulated bushings extending through the metal housings

2 and 15.[38] Presumably, these bushings are sufficient to prevent lead 9 from shorting with metal housings 2 and 15, and to prevent bodily fluid from entering housings 2 and 15. Hirschberg fails to disclose any additional sealing or insulation regarding the connection of lead 9 and the housings.

Moreover, there is nothing in Hirschberg that suggests that the connection of first section 18 of lead 9 with such bushings 7 and 16 would inherently meet the requirement of claim 7 of a coupling module that is made of a metal that defines at least one lumen and is hermetically fixed to the first and second housings. To the extent the Hirschberg bushings provide any sealing, they would appear to seal the housings 2 and 15 at the point at which a conductor of lead 9 enters, e.g., is fed through, the housings. Thus, any seal would be between the bushings 7 and 16 and the conductor within lead 9. Nothing in Hirschberg would remotely suggest any seal, much less a hermetic seal, between any portion of lead 9 that defines a lumen and either bushings 7 and 16, or housings 2 and 15. Thus, Hirschberg cannot be considered to even suggest, much less inherently disclose, a coupling module that is made of a metal that defines at least one lumen and is hermetically fixed to the first and second housings

Hirschberg fails to teach or suggest each and every element of claim 7. Dependent claims 8, 11 and 20-23 are patentable for at least the reasons claim 7 is patentable. For at least these reasons, the rejection of claims 7, 8, 11 and 20-23 is improper and should be reversed.

GROUP 3 - (Claim 9)

Dependent claim 9 is patentable for at least the reasons independent claim 7 is patentable. In addition, dependent claim 9 recites that the coupling module defines at least two lumens. Hirschberg fails to teach or suggest a coupling module defining at least two lumens, and the Office Action failed to account for such a feature. For example, Hirschberg does not disclose that lead 9 includes at least two lumens.

Hirschberg fails to teach or suggest each and every element of independent claim 7 as well as elements recited in claim 9. For at least these reasons, the rejection of claim 9 is improper and should be reversed.

[38] Hirschberg et al. column 3, lines 31-34.

GROUP 4 - (Claim 10)

Dependent claim 10 is patentable for at least the reasons independent claim 7 and intervening claim 9 are patentable. In addition, dependent claim 10 recites that the lumens comprise co-axial lumens. With respect to claim 10, Hirschberg fails to teach or suggest a coupling module defining two coaxial lumens, and the Office Action failed to account for such a feature. Nothing in Hirschberg remotely suggests that lead 9 includes coaxial lumens, as required by claim 10.

Hirschberg fails to teach or suggest each and every element of independent claim 7 and intervening claim 9 as well as elements recited in claim 10. For at least these reasons, the rejection of claim 10 is improper and should be reversed.

GROUP 5 - (Claim 14)

Dependent claim 14 is patentable for at least the reasons independent claim 7 is patentable. In addition, dependent claim 14 recites that the coupling module includes at least one of a corrugation, convolution, and a variation in cross-sectional shape. With respect to claim 14, Hirschberg fails to teach or suggest a coupling module including at least one of a corrugation, convolution, and a variation in cross-sectional shape, and the Office Action failed to account for such a feature.

Hirschberg fails to teach or suggest each and every element of independent claim 7 as well as elements recited in claim 14. For at least these reasons, the rejection of claim 14 is improper and should be reversed.

GROUP 6 - (Claim 15)

Dependent claim 15 is patentable for at least the reasons independent claim 7 is patentable. In addition, dependent claim 15 recites that the coupling module includes at least a helical portion. With respect to claim 15, Hirschberg fails to teach or suggest a coupling module including at least a helical portion, and the Office Action failed to account for such a feature. Nothing in Hirschberg remotely suggests that lead 9 includes a helical portion, as required by claim 15. For example, the figures in Hirschberg do not depict lead 9 as including a helical portion.

Hirschberg fails to teach or suggest each and every element of independent claim 7 as well as elements recited in claim 15. For at least these reasons, the rejection of claim 15 is improper and should be reversed.

GROUP 7 - (Claim 17)

Dependent claim 17 is patentable for at least the reasons independent claim 7 is patentable. In addition, dependent claim 17 recites that the metal [of the coupling module] comprises titanium. With respect to claim 17, Hirschberg fails to teach or suggest a coupling module made of a metal comprising titanium. Hirschberg mentions that housings 2 and 15 may consist of titanium,[39] but certainly fails to disclose or suggest that lead 9 may be made of a metal comprising titanium that defines at least one lumen.

Hirschberg fails to teach or suggest each and every element of independent claim 7 as well as elements recited in claim 17. For at least these reasons, the rejection of claim 17 is improper and should be reversed.

THIRD GROUND OF REJECTION UNDER APPEAL

The Office Action rejected claims 12, 13, 18 and 19 under 35 U.S.C. § 103(a) as being unpatentable over Hirschberg. Appellant notes that claim 12 is now cancelled, rendering its rejection moot. Appellant respectfully traverses the rejection of claims 13, 18 and 19. The applied reference fails to teach or suggest the inventions defined by Appellant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention. Appellant notes that claims 13, 18 and 19 are patentable for at least the reasons independent claim 7 is patentable.

For example, with respect to independent claim 7, Hirschberg fails to teach or suggest the feature of wherein the coupling module is made of a metal that defines at least one lumen. As another example with respect to independent claim 7, Hirschberg fails to teach or suggest the feature of wherein the coupling module is hermetically fixed to the first and second housings.

[39] Hirschberg et al., column 3, lines 31-32.

GROUP 8 - (Claim 13)

Dependent claim 13 is patentable for at least the reasons independent claim 7 is patentable. In addition, dependent claim 13 recites that the coupling module includes a bellows section. Hirschberg fails to disclose a bellows section. For this reason alone, the rejection of claim 13 should be reversed.

Additionally, a bellows section would serve no apparent purpose in the implantable defibrillator disclosed by Hirschberg. In the rejection of claim 13, the Office Action stated that it would have been obvious to included a bellows section to permit axial flexibility the implantable defibrillator disclosed by Hirschberg. However, leads 9 presumably include a plastic or like coating over a flexible metal conductor. Thus, leads 9 would likely have substantial axial flexibility without the inclusion of a bellows section. For at least these reasons, the feature of wherein the coupling module includes a bellows section would not have been obvious to one of ordinary skill in the art based on the teachings of Hirschberg.

Hirschberg fails to teach or suggest each and every element of independent claim 7 as well as elements recited in claim 13. For at least these reasons, the rejection of claim 13 is improper and should be reversed.

GROUP 9 - (Claim 18)

Dependent claim 18 is patentable for at least the reasons independent claim 7 is patentable. In addition, dependent claim 18 recites that the coupling module is fixedly coupled to at least one housing with a weld joint. In the rejection of claim 18, the Office Action stated that it would have been obvious to weld titanium to make a hermetic seal to prevent corrosion and seal out bodily fluids in the implantable defibrillator disclosed by Hirschberg. However, leads 9 are not made of metal forming a lumen, much less titanium, and it is not clear how welding could be used without damaging the leads, which presumably include a plastic coating or the like covering a metal conductor.

Hirschberg fails to teach or suggest each and every element of independent claim 7 as well as elements recited in claim 18. For at least these reasons, the rejection of claim 18 is improper and should be reversed.

GROUP 10 - (Claim 19)

Dependent claim 19 is patentable for at least the reasons independent claim 7 is patentable. Hirschberg fails to teach or suggest each and every element of independent claim 7. For example, with respect to independent claim 7, Hirschberg fails to teach or suggest the feature of wherein the coupling module is made of a metal that defines at least one lumen. As another example with respect to independent claim 7, Hirschberg fails to teach or suggest the feature of wherein the coupling module is hermetically fixed to the first and second housings. For at least these reasons, the rejection of dependent claim 19 is improper and should be reversed.

FOURTH GROUND OF REJECTION UNDER APPEAL

The Office Action rejected claims 1, 3-6 and 24 under 35 U.S.C. § 103(a) as being unpatentable over Lynch. Appellant respectfully traverses the rejection of claims 1, 3-6 and 24. The applied reference fails to teach or suggest the inventions defined by Appellant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Appellant's independent claim 1 is directed to an implantable medical device comprising at least two modules, each of the modules comprising a respective one of at least two housings, a coupling module coupled to each of the modules, the coupling module defining at least one lumen between the housings, and an overmold that at least partially encapsulates each of the housings and the coupling module. The coupling module permits motion of the two modules along at least one axis of motion.

GROUP 11 - (Claims 1, 3, 5 and 24)

With respect to independent claim 1, Lynch fails to teach or suggest an implantable medical device comprising at least two modules, each of the modules comprising a respective one of at least two housings, a coupling module coupled to each of the modules, the coupling module defining at least one lumen between the housings, and an overmold that at least partially encapsulates each of the housings and the coupling module, wherein the coupling module permits motion of the two modules along at least one axis of motion.

In the rejection of claim 1 the Office Action admits that Lynch fails to teach an overmold that at least partially encapsulates each of the housings and the coupling module as recited in claim 1. However, the Office Action argued that it would be obvious to coat both the case 12 and the lead 3 with a dip coating of silicone because Lynch teaches the layer of soft silicon 25 is applied after the lead and the case have been assembled and because a dip coating is also an after an assembly process. For reference, a portion of Lynch that discusses silicon 25 is shown below.

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At the point where the leads 3 enter the case 12, a layer of soft silicone rubber 25 is applied to absorb any lateral strain on the leads 3. This layer of soft silicone 25 is applied after the case 12 and leads 3 have been assembled and can be removed, for example, by cutting, if a lead 3 needs to be replaced..

The Office Action fails to provide any reasoning whatsoever as to why one of ordinary skill in the art would find it obvious to modify silicon 25 other than to say that, "a dip coating is also an after an assembly process." Lynch fails to provide any reason to include more silicon than that shown in FIG. 3, which is what the Examiner proposes. In fact, Lynch teaches a benefit of the layer of silicon 25 that may not be the same with a dip coating– the benefit that the layer of silicon 25 can be removed if a lead 3 needs to be replaced. In contrast, a dip coating of silicon on each of cuff 2, lead 3 and case 12 would likely be more difficult to remove than a layer of silicon 25 only where lead 3 enters case 12, which could make it more difficult to replace a lead. Thus, in view of this teaching of Lynch, a person of ordinary skill would have avoided modification of Lynch in the manner suggested by the Examiner.

Furthermore, because a dip coating on each of cuff 2, lead 3 and case 12 would be more extensive than a dip coating at cuff 2 and a separate layer of silicone 25 only where lead 3 enters case 12, it may not provide the same advantages or serve the same purposes as the dip coating at cuff 2 and the separate layer of silicone 25 at only where lead 3 enters case 12. For example, a dip coating on each of cuff 2, lead 3 and case 12 may not absorb lateral strain on leads 3 in the same way as a separate layer of silicone 25 at only where lead 3 enters case 12. In this manner, the modification proposed by the Examiner may frustrate the intended purpose of the separate layer of silicone 25 located only where lead 3 enters case 12. Because there is no logical reason to undertake the modification proposed in the Office Action, and because it may negatively affect

the ability of Lynch device to operate as intended, a person of ordinary skill in the art would not have undertaken such medication or considered it obvious.

In this manner, Lynch fails to teach or suggest Appellant's invention as recited in claim 1. Dependent claims 3, 5 and 24 are patentable for at least the reasons claim 1 is patentable. For at least these reasons, the rejection of claims 1, 3, 5 and 24 is improper and should be reversed.

GROUP 12 - (Claim 4)

Dependent claim 4 is patentable for at least the reasons independent claim 1 is patentable. In addition, dependent claim 4 recites that the coupling module defines at least two lumens. However, Lynch fails to teach or suggest a coupling module defining at least two lumens. For example, Lynch does not disclose that lead 3 includes at least two lumens. Indeed, the Office Action fails to even address this feature.

Lynch fails to teach or suggest each and every element of independent claim 1 as well as elements recited in claim 4. For at least these reasons, the rejection of claim 4 is improper and should be reversed.

GROUP 13 - (Claim 6)

Dependent claim 6 is patentable for at least the reasons independent claim 1 is patentable. In addition, dependent claim 6 recites that the implantable medical device has a maximum thickness of between approximately 4 millimeters and approximately 8 millimeters. Lynch fails to teach or suggest the feature of wherein the implantable medical device has a maximum thickness of between approximately 4 millimeters and approximately 8 millimeters. Again, the Office Action fails to even address this feature.

Lynch fails to teach or suggest each and every element of independent claim 1 as well as elements recited in claim 6. For at least these reasons, the rejection of claim 6 is improper and should be reversed.

FIFTH GROUND OF REJECTION UNDER APPEAL

The Office Action rejected claims 7, 8, 19 and 25 under 35 U.S.C. § 103(a) as being unpatentable over Meltzer (US 5,645,586). Appellant respectfully traverses the rejection. The

applied reference fails to teach or suggest the inventions defined by Appellant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

GROUP 14 - (Claims 7, 8 and 19)

Appellant's independent claim 7 is directed to an implantable medical device comprising at least two modules, each of the modules comprising a respective one of at least two housings, a coupling module coupled to each of the modules, the coupling module defining at least one lumen between the housings, and an overmold that at least partially encapsulates each of the housings and the coupling module. The coupling module permits motion of the two modules along at least one axis of motion.

In the rejection of independent claim 7, the Office Action correctly recognized that Meltzer fails to teach or suggest a coupling module that defines at least one lumen between the first and second housings. Nonetheless, the Office Action concluded that such a feature would have been obvious. Appellant respectfully disagrees.

A finding of obviousness under 35 U.S.C. § 103(a) requires that all of the claimed elements were known in the prior art.[40] In this instance, the Office Action freely admits that each of the claimed elements were not found in the cited reference and fails to provide any indication that the claimed elements not found in the cited reference were known in the prior art. Therefore, the rejection of independent claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Meltzer is improper and should be withdrawn.

Additionally, the mere fact that Meltzer mentions that the manner in which housing segments may be joined takes many forms as cited in the Office Action[41] is completely insufficient to provide support for a prima facie case of obviousness regarding the feature of a coupling module made of a metal that defines at least one lumen between the first and second housings as recited by claim 7. Instead, for example as shown in FIGS. 2-4, Meltzer discloses a housing with multiple segments that pivot about "hinge axis". While Meltzer does state that the manner in which the housing segments are joined for pivotable movement may take many

[40] *KSR*, 550 U.S. at ___, 82 USPQ2d at 1395, as cited in MPEP 2143.
[41] Page 4.

forms,[42] this statement is made in the context of FIG. 3, which illustrates a specific embodiment of the disclosed hinge axis. Nothing in Meltzer suggests a coupling module defining at least one lumen between two housings. Meltzer clearly fails to disclose or suggest such as feature and the Examiner has failed to provide a rational reason as to why one of ordinary skill in the art would have found such a feature to be obvious.

In this manner, Meltzer fails to teach or suggest Appellant's invention as recited in claim 7. Dependent claims 8 and 19 are patentable for at least the reasons claim 1 is patentable. For at least these reasons, the rejection of claims 7, 8 and 19 is improper and should be reversed.

GROUP 15 - (Claim 25)

Appellant's independent claim 25 is directed to an implantable medical device comprising a first module that includes control electronics comprising a first housing; a second module comprising a second housing; and a coupling module fixedly coupled to the first and second housings. The coupling module is hermetically fixed to the first and second housings[43] and defines at least one lumen between the first and second housings. The coupling module permits motion of the first housing relative to the second housing and along at least one axis of motion.

In the rejection of independent claim 25, the Office Action correctly recognized that Meltzer fails to teach or suggest a coupling module that defines at least one lumen between the first and second housings. Nonetheless, the Office Action concluded that such a feature would have been obvious. Appellant respectfully disagrees.

A finding of obviousness under 35 U.S.C. § 103(a) requires that all of the claimed elements were known in the prior art.[44] In this instance, the Office Action freely admits that each of the claimed elements were not found in the cited reference and fails to provide any indication that the claimed elements not found in the cited reference were known in the prior art. Therefore, the rejection of independent claim 25 under 35 U.S.C. § 103(a) as being unpatentable over Meltzer is improper and should be withdrawn.

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[42] Column 4, lines 13-16.
[43] *See, e.g.*, Application, paragraphs [0061] and [0068].
[44] *KSR*, 550 U.S. at ___, 82 USPQ2d at 1395, as cited in MPEP 2143.

In this manner, Meltzer fails to teach or suggest Appellant's invention as recited in claim 25. For at least these reasons, the rejection of claim 25 is improper and should be reversed.

SIXTH GROUND OF REJECTION UNDER APPEAL

GROUP 16 - (Claim 1)

Appellant's independent claim 1 is directed to an implantable medical device comprising at least two modules, each of the modules comprising a respective one of at least two housings, a coupling module coupled to each of the modules, the coupling module defining at least one lumen between the housings, and an overmold that at least partially encapsulates each of the housings and the coupling module. The coupling module permits motion of the two modules along at least one axis of motion.

The Office Action rejected claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending US Pat. No. 7,212,864.

Appellant respectfully traverses this rejection. Appellant respectfully submits that the Office Action has not established a prima facie case of obviousness-type double patenting. To support an obviousness-type double patenting rejection, the Office Action must assess the differences between the claims in the pending application and the claims in the issued patent.[45] In particular, the Office Action should indicate why the claims in an application are obvious over the claims in the granted patent.[46]

The Office Action stated that the application and patent claims are not patentably distinct "because the two modules of the claimed invention possess an identical housing to that of the [issued patent]." Proper analysis employed in an obviousness-type double patenting rejection is the same as analysis for a 35 U.S.C. § 103 obviousness determination.[47] Therefore, all of the claimed features recited by claim 1, in combination, must be obvious in view of claim 1 of US Pat. No. 7,212,864.

In contrast to the present invention as recited in claim 1, claim 1 of US Pat. No. 7,212,864 does not include or suggest, "a coupling module coupled to each of the modules, the coupling

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[45] *In re Berg*, 46 USPQ2d 1226, 1229 (Fed Cir. 1998).
[46] *Id.*
[47] *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985), as cited in MPEP 804.

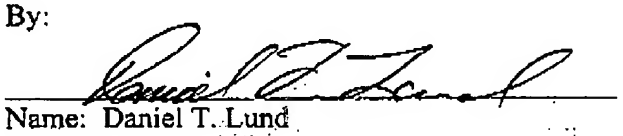
module defining at least one lumen between the housings," as recited in claim 1 of the present application. Because each of the features of claim 1 are not obvious in view of claim 1 of US Pat. No. 7,212,864, the rejection of claim 1 is improper and should be reversed.

CONCLUSION OF ARGUMENT

All claims in this application are in condition for allowance. In view of Appellant's arguments, the final rejections of claims 1, 3-11, 13-15 and 17-25 are improper and should be reversed, and all of the pending claims should be allowed. Appellant respectfully requests separate review by the Board for each of the groups addressed above under separate headings.

Respectfully submitted,

Date: April 22, 2008

By: 

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CLAIMS APPENDIX

1. An implantable medical device comprising:

at least two modules, each of the modules comprising a respective one of at least two housings;

a coupling module coupled to each of the modules, the coupling module defining at least one lumen between the housings; and

an overmold that at least partially encapsulates each of the housings and the coupling module,

wherein the coupling module permits motion of the two modules along at least one axis of motion.

3. The implantable medical device of claim 1, wherein the coupling module permits motion of the two modules along at least two axes of motion.

4. The implantable medical device of claim 1, wherein the coupling module defines at least two lumens.

5. The implantable medical device of claim 1, wherein at least one of the two modules comprises a control module containing electronic components.

6. The implantable medical device of claim 1, wherein the implantable medical device has a maximum thickness of between approximately 4 millimeters and approximately 8 millimeters.

7. An implantable medical device comprising:

a first module that includes control electronics comprising a first housing;

a second module comprising a second housing; and

a coupling module fixedly coupled to the first and second housings,

wherein the coupling module is hermetically fixed to the first and second housings, wherein the coupling module is made of a metal that defines at least one lumen between the first and second housings, and wherein the coupling module permits motion of the first housing relative to the second housing and along at least one axis of motion.

8. The device of claim 7, wherein the coupling module permits motion of the multiple modules along at least two axes of motion.

9. The device of claim 7, wherein the coupling module defines at least two lumens.

10. The device of claim 9, wherein the lumens comprise co-axial lumens.

11. The device of claim 7, wherein the coupling module defines one of a circular cross-sectional shape, a semi-circular cross-sectional shape and a rectangular cross-sectional shape.

13. The device of claim 7, wherein the coupling module includes a bellows section.

14. The device of claim 7, wherein the coupling module includes at least one of a corrugation, convolution, and a variation in cross-sectional shape.

15. The device of claim 7, wherein the coupling module includes at least a helical portion.

17. The device of claim 7, wherein the metal comprises titanium.

18. The device of claim 7, wherein the coupling module is fixedly coupled to at least one housing with a weld joint.

19. The device of claim 7, further comprising:

a third module; and

a second coupling module fixedly coupled to the third module and to at least one of the first and second housings.

20. The device of claim 7, wherein the second module comprises a battery.

21. The device of claim 7, wherein the coupling module is fixedly coupled to portions of the housings that are adjacent to one other.

22. The device of claim 7, wherein the coupling module comprises at least one bend.

23. The device of claim 7, further comprising a conductor passing through the lumen that electrically couples the first and second modules.

24. The device of claim 1, further comprising a conductor passing through the lumen that electrically couples the first and second modules.

25. An implantable medical device comprising:

a first module that includes control electronics comprising a first housing;

a second module comprising a second housing; and

a coupling module fixedly coupled to the first and second housings,

wherein the coupling module is hermetically fixed to the first and second housings and defines at least one lumen between the first and second housings, and wherein the coupling module permits motion of the first housing relative to the second housing and along at least one axis of motion.

EVIDENCE APPENDIX

NONE

RELATED PROCEEDINGS APPENDIX

NONE